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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15-XI-2005  
C(2005)4501

NOT FOR PUBLICATION

**COMMISSION DECISION**

**of 15-XI-2005**

**amending the marketing authorisation for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use, granted by Decision C(2004)3160**

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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## COMMISSION DECISION

of 15-XI-2005

**amending the marketing authorisation for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use, granted by Decision C(2004)3160**

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products<sup>1</sup>,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93<sup>2</sup>, and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 15 August 2005 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 13 October 2005,

Whereas:

- (1) An examination of the major variation type II to the terms of the marketing authorisation for the medicinal product "Ariclaim - duloxetine hydrochloride", which is entered in the Community Register of Medicinal Products under No(s) EU/1/04/283/001-007 and the placing on the market of which was authorised by Decision C(2004)3160 of 11 August 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the

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<sup>1</sup> OJ L 214, 24.8.1993, p. 1. Regulation as last amended by Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19).

<sup>2</sup> OJ L 159, 27.6.2003, p. 24.

European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>3</sup>.

- (2) It is therefore appropriate to accept the application in respect of a major variation to the terms of the marketing authorisation and to amend Decision C(2004)3160 accordingly.
- (3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)3160 should therefore be replaced,

HAS ADOPTED THIS DECISION:

#### *Article 1*

Decision C(2004)3160 is amended as follows:

- 1) Annex I is replaced by the text set out in Annex I to this Decision;
- 2) Annex III B is replaced by the text set out in Annex III B to this Decision.

#### *Article 2*

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 15-XI-2005

*For the Commission*  
*Günter VERHEUGEN*  
*Vice-President of the Commission*

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<sup>3</sup> OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).